IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELI LILLY & CO., INCYTE CORP. and INCYTE HOLDINGS CORP.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA U.S.A., INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Eli Lilly and Company ("Lilly"), Incyte Corporation, and Incyte Holdings Corporation (collectively "Plaintiffs") by their attorneys, hereby allege against Defendants Aurobindo Pharma Limited and Aurobindo Pharma U.S.A., Inc. (collectively, "Aurobindo") as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Aurobindo of Abbreviated New Drug Application ("ANDA") No. 217542 ("the Aurobindo ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell generic versions of Olumiant® (baricitinib) tablets, 1 mg and 2 mg strengths ("Aurobindo's Proposed ANDA Product"), prior to the expiration of U.S. Patent Nos. 8,158,616 ("the '616 Patent") and 8,420,629 ("the '629 Patent") (collectively "the Asserted Patents"). By letter dated July 13, 2022, Aurobindo notified Plaintiffs that it had submitted this ANDA ("Notice Letter"). Upon information and belief, Aurobindo's Proposed ANDA Product will be marketed as a competing product to Olumiant® (baricitinib), a product approved for the treatment of adult

patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF blockers. Olumiant® (baricitinib) is also approved for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO, and for the treatment of adult patients with severe alopecia areata.

PARTIES

2. Plaintiff Lilly is a corporation organized and existing under the laws of Indiana, having a place of business at Lilly Corporate Center, Indianapolis, IN 46285.

3. Plaintiff Incyte Corporation is a corporation organized and existing under the laws of Delaware, having a place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803.

4. Plaintiff Incyte Holdings Corporation is a corporation organized and existing under the laws of Delaware, having a place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803.

5. Upon information and belief, Defendant Aurobindo Pharma Limited is a corporation organized and existing under the laws of the Republic of India, having a place of business at Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Ranga Reddy, India. Upon information and belief, Aurobindo Pharma Limited is in the business of, among other things, manufacturing, selling, importing, and distributing generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Aurobindo Pharma U.S.A., Inc., throughout the United States, including in Delaware.

6. Upon information and belief, Aurobindo Pharma U.S.A., Inc. is a corporation organized and existing under the laws of Delaware, having its corporate offices and a place of business at 279 Princeton-Hightstown Road, East Windsor, NJ 08520. Upon information and

belief, Aurobindo Pharma U.S.A., Inc. is a wholly owned subsidiary of Aurobindo Pharma Limited. Upon information and belief, Aurobindo Pharma U.S.A., Inc. is in the business of, among other things, selling, importing, and distributing generic versions of branded pharmaceutical drug products throughout the United States, including in Delaware.

7. Upon information and belief, Aurobindo Pharma Limited and Aurobindo Pharma U.S.A., Inc. collaborate with respect to the development, regulatory approval, marketing, manufacture, sale, importation, and/or distribution of pharmaceutical products. Upon further information and belief, Aurobindo Pharma Limited and Aurobindo Pharma U.S.A., Inc. are agents and/or alter egos of each other and/or operate in concert as integrated parts of the same business group.

8. Upon information and belief, Aurobindo Pharma Limited and Aurobindo Pharma U.S.A., Inc. acted in concert to develop Aurobindo's Proposed ANDA Product that is the subject of the Aurobindo ANDA and to seek regulatory approval from the FDA to market and sell Aurobindo's Proposed ANDA Product throughout the United States, including in Delaware.

9. Upon information and belief, Aurobindo Pharma Limited and Aurobindo Pharma U.S.A., Inc. intend to benefit directly if the Aurobindo ANDA is approved by participating in the development, regulatory approval, marketing, manufacture, importation, distribution, and/or sale of Aurobindo's Proposed ANDA Product.

10. Upon information and belief, Aurobindo Pharma Limited and Aurobindo Pharma U.S.A., Inc. intend to act collaboratively to obtain approval for the Aurobindo ANDA, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import Aurobindo's Proposed ANDA Product in the United States, including in Delaware.

11. Upon information and belief, Aurobindo Pharma Limited submitted the Aurobindo ANDA seeking approval to market and sell baricitinib tablets in 1 mg and 2 mg strengths for treatment of moderately to severely active rheumatoid arthritis.

12. Upon information and belief, Aurobindo Pharma U.S.A., Inc. intends to and will offer for sale, sell, and distribute Aurobindo's ANDA Product in the United States, including in Delaware, in the event the FDA approves the Aurobindo ANDA.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

14. This Court has personal jurisdiction over Aurobindo Pharma Limited because, among other things, on information and belief: (1) Aurobindo Pharma Limited submitted the Aurobindo ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of Aurobindo's Proposed ANDA Product in the United States, including in Delaware; and (2) upon approval of the Aurobindo ANDA, Aurobindo Pharma Limited and its subsidiary, agent, and/or alter ego Aurobindo Pharma U.S.A., Inc. will market, distribute, offer for sale, sell, and/or import Aurobindo's Proposed ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Aurobindo's Proposed ANDA Product in Delaware. On information and belief, upon approval of the Aurobindo ANDA, Aurobindo's Proposed ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware.

15. In addition, this Court has personal jurisdiction over Aurobindo Pharma Limited because, *inter alia*, Aurobindo Pharma Limited, itself and through its subsidiary, agent, and/or alter ego Aurobindo Pharma U.S.A., Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Aurobindo Pharma Limited, itself and through its subsidiary, agent, and/or alter ego Aurobindo Pharma U.S.A., Inc., develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

16. In addition, this Court has personal jurisdiction over Aurobindo Pharma Limited because it has committed, aided, abetted, induced, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Incyte Corporation and Incyte Holdings Corporation, both Delaware corporations.

17. Because plaintiffs Incyte Corporation and Incyte Holdings Corporation are incorporated and have places of business in Delaware, the injury and consequence of Aurobindo Pharma Limited's submission of the Aurobindo ANDA, challenging Plaintiffs' patent rights, are suffered in Delaware. Upon information and belief, Aurobindo Pharma Limited knew that it was deliberately challenging the patent rights of Delaware entities and seeking to challenge intellectual property held in Delaware and that the effects of any successful challenge of the Asserted Patents would be felt by Plaintiffs in Delaware.

18. In addition, this Court has personal jurisdiction over Aurobindo Pharma Limited because it regularly engages in patent litigation concerning Aurobindo's ANDA products in this District, does not contest personal jurisdiction in this District, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Gilead Sciences, Inc. v. Aurobindo Pharma Ltd., et al.*, C.A. No. 21-1735-WCB (D. Del.); *Allergan, Inc., v. Aurobindo Pharma Ltd*., C.A. No. 21-1808 (D. Del); *Pfizer Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 20-1528 (D. Del.).

19. Alternatively, to the extent personal jurisdiction over Aurobindo Pharma Limited in Delaware is not held to be proper, then, upon information and belief, Aurobindo Pharma Limited is not subject to jurisdiction in any state's courts of general jurisdiction. Therefore, there is personal jurisdiction over Aurobindo Pharma Limited in this Court pursuant to Federal Rule of Civil Procedure 4(k)(2) and exercising jurisdiction over it is consistent with the United States Constitution and laws.

20. For at least the above reasons, it would not be unfair or unreasonable for Aurobindo Pharma Limited to litigate this action in this District, and Aurobindo Pharma Limited is subject to personal jurisdiction in this District.

21. This Court has personal jurisdiction over Aurobindo Pharma U.S.A., Inc. because, on information and belief, Aurobindo Pharma U.S.A., Inc. is a corporation organized and existing under the laws of the Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. Therefore, Aurobindo Pharma U.S.A., Inc. has consented to general jurisdiction in Delaware.

22. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and/or 1400(b) with respect to Aurobindo Pharma Limited, at least because, on information and belief, Aurobindo Pharma Limited is a foreign corporation that may be sued in any judicial district.

23. Venue is proper in this District under 28 U.S.C. §§ 1391(c) and/or 1400(b) with respect to Aurobindo Pharma U.S.A., Inc., at least because, on information and belief, Aurobindo Pharma U.S.A., Inc. is a corporation organized and existing under the laws of Delaware and therefore resides in Delaware for purposes of venue.

BACKGROUND

OLUMIANT® (BARICITINIB)

24. On May 31, 2018 and October 8, 2019, the FDA granted Lilly approval to market Olumiant® (baricitinib) for the treatment of moderately to severely active rheumatoid arthritis in adult patients who have an inadequate response to one or more TNF antagonist therapies. On May 10, 2022, the FDA granted Lilly supplemental approval to market Olumiant® (baricitinib) for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO. On June 13, 2022, the FDA granted Lilly supplemental approval to market Olumiant® (baricitinib) for the treatment of adult patients with severe alopecia areata.

25. The active pharmaceutical ingredient in Olumiant® is baricitinib. Baricitinib is a Janus kinase (JAK) inhibitor with the chemical name {1-(ethylsulfonyl)-3-[4-(7*H*-pyrrolo[2,3-*d*]pyrimidin-4-yl)-1*H*-pyrazol-1-yl]azetidin-3-yl}acetonitrile. Olumiant® (baricitinib) is FDA approved in 1, 2, and 4 mg dosage strengths. The recommended dosage for the treatment of adult patients with moderately to severely active rheumatoid arthritis is 2 mg once daily, with a modified dosage to 1 mg under certain conditions. The recommended dosage for the treatment of COVID-

19 is 4 mg once daily, with modified doses to 1 mg and 2 mg under certain conditions. The recommended dosage for the treatment of severe alopecia areata is 2 mg once daily, with modified doses to 4 mg or 1 mg under certain conditions.

26. Lilly markets Olumiant® (baricitinib) in the United States pursuant to approved New Drug Application ("NDA") No. 207924.

27. Lilly is the holder of approved NDA No. 207924 for Olumiant® (baricitinib).

28. The '616 and '629 Patents are listed for NDA No. 207924 for Olumiant® (baricitinib) in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book."

29. The Asserted Patents cover, *inter alia*, baricitinib, pharmaceutical compositions containing baricitinib, and methods of use and administration of baricitinib or pharmaceutical compositions containing baricitinib.

30. The '616 Patent, titled "Azetidine and Cyclobutane Derivatives as JAK Inhibitors" was duly and legally issued on April 17, 2012. A copy of the '616 Patent is attached as Exhibit A.

31. Incyte Corporation and Incyte Holdings Corporation are the assignees and owners of the '616 Patent.

32. Lilly is the exclusive licensee of the '616 Patent.

33. There is an actual case or controversy between the parties regarding Aurobindo's liability for its infringement of the '616 Patent.

34. The '629 Patent, titled "Azetidine and Cyclobutane Derivatives as JAK Inhibitors," was duly and legally issued on April 16, 2013. A copy of the '629 Patent is attached as Exhibit B.

35. Incyte Corporation and Incyte Holdings Corporation are the assignees and owners of the '629 Patent.

36. Lilly is the exclusive licensee of the '629 Patent.

37. There is an actual case or controversy between the parties regarding Aurobindo's liability for its infringement of the '629 Patent.

AUROBINDO'S ANDA

38. Aurobindo's Notice Letter informed Plaintiffs that Aurobindo seeks, through the Aurobindo ANDA, FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of Aurobindo's Proposed ANDA Product prior to the expiration of the Asserted Patents. According to the Notice Letter, included within the Aurobindo ANDA is a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the Asserted Patents are invalid and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale of Aurobindo's Proposed ANDA Product.

39. Aurobindo was aware of the Asserted Patents when it submitted the Aurobindo ANDA with a Paragraph IV Certification.

40. On information and belief, baricitinib is the active ingredient in Aurobindo's Proposed ANDA Product. On information and belief, Aurobindo's Proposed ANDA Product is a pharmaceutical formulation comprising baricitinib oral tablets in 1 mg and 2 mg strengths.

41. On information and belief, the Aurobindo ANDA refers to and relies upon the NDA for Olumiant® (baricitinib) and contains data that, according to Aurobindo, demonstrates bioequivalence of Aurobindo's Proposed ANDA Product and Olumiant® (baricitinib), *see* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

42. On information and belief, Aurobindo intends to sell its Proposed ANDA Product with a label that, *inter alia*, instructs and encourages the administration of 1 mg and 2 mg baricitinib tablets for the treatment of rheumatoid arthritis.

43. On information and belief, Aurobindo intends that its Proposed ANDA Product be used as set forth in its Proposed ANDA Product label.

44. This action is being filed within 45 days of Plaintiffs' receipt of Aurobindo's Notice Letter.

COUNT I
(Infringement of the '616 Patent)

45. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

46. Claim 1 of the '616 Patent covers the compound {1-(Ethylsulfonyl)-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]azetidin-3-yl}acetonitrile, or a pharmaceutically acceptable salt thereof.

47. Upon information and belief, Aurobindo's Proposed ANDA Product is covered by one or more claims of the '616 Patent, including at least claim 1, because it contains baricitinib, which is a compound with the chemical name {1-(Ethylsulfonyl)-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]azetidin-3-yl}acetonitrile.

48. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's Proposed ANDA Product, or the use of Aurobindo's Proposed ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product, will infringe one or more claims of the '616 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

49. Upon information and belief, Aurobindo submitted as part of the Aurobindo ANDA a Paragraph IV Certification, asserting that the claims of the '616 Patent are invalid and/or not infringed by the manufacture, use, offer for sale, or sale of Aurobindo's Proposed ANDA Product.

50. Aurobindo did not contend in its Notice Letter that Aurobindo's Proposed ANDA Product, or the use of Aurobindo's Proposed ANDA Product in accordance with and as directed

by Aurobindo's proposed labeling for that product, would not infringe claims 1-3 of the '616 Patent.

51. Aurobindo has no reasonable basis to believe that Aurobindo's Proposed ANDA Product, or the use of Aurobindo's Proposed ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product, would not infringe one or more claims of the '616 Patent.

52. The purpose of submitting the Aurobindo ANDA to the FDA was to obtain approval under the Federal Food Drug and Cosmetic Act ("FDCA"), to engage in the commercial manufacture, use, offer for sale, importation, and/or sale of Aurobindo's Proposed ANDA Product prior to the expiration of the '616 Patent.

53. Aurobindo's submission of the Aurobindo ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, importation, and/or offer for sale of Aurobindo's Proposed ANDA Product prior to the expiration of the '616 Patent was an act of infringement of the '616 Patent under 35 U.S.C. § 271(e)(2)(A).

54. Upon information and belief, Aurobindo intends to engage in the commercial manufacture, use, sale, importation, and/or offer for sale of Aurobindo's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of the Aurobindo ANDA and any amendments thereto, *i.e.*, prior to the expiration of the '616 Patent.

55. Upon information and belief, Aurobindo has knowledge of the '616 Patent at least because the '616 Patent is listed in the Orange Book for Lilly's Olumiant® (baricitinib) drug product. Notwithstanding this knowledge, Aurobindo continues to assert its intent to engage in the manufacture, use, offer for sale, importation, and/or sale of Aurobindo's Proposed ANDA

Product and the proposed labeling therefor immediately and imminently upon the approval of the Aurobindo ANDA and any amendments thereto.

56. Upon information and belief, Aurobindo intends to sell its Proposed ANDA Product with a label that includes instructions to administer 1 mg and 2 mg baricitinib tablets for the treatment of rheumatoid arthritis in a manner that will infringe claim 1 of the '616 Patent.

57. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '616 Patent when the Aurobindo ANDA and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '616 Patent. Further upon information and belief, Aurobindo plans and intends to, and will, do so immediately and imminently upon approval.

58. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '616 Patent and active inducement of infringement of the '616 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a) and (b).

59. Unless Aurobindo is enjoined from infringing the '616 Patent and actively inducing infringement of the '616 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the '629 Patent)

60. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

61. Claim 1 of the '629 Patent covers "[a] method of treating rheumatoid arthritis in a patient comprising administering to said patient a therapeutically effective amount of {1-(ethylsulfonyl)-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]azetidin-3-yl}acetonitrile, or a pharmaceutically acceptable salt thereof, provided that treating is not preventing."

62. Upon information and belief, use of Aurobindo's Proposed ANDA Product is covered by claim 1 of the '629 Patent, because the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product involves treating rheumatoid arthritis in a patient by administering baricitinib, which is a compound with the chemical name {1-(Ethylsulfonyl)-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]azetidin-3-yl}acetonitrile.

63. Upon information and belief, Aurobindo intends to sell its Proposed ANDA Product with a label that, *inter alia*, encourages and instructs the administration of 1 mg and 2 mg baricitinib tablets for the treatment of rheumatoid arthritis in a manner that will infringe claim 1 of the '629 Patent.

64. Upon information and belief, the use of Aurobindo's Proposed ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product will infringe claim 1 of the '629 Patent, either literally or under the doctrine of equivalents.

65. Upon information and belief, Aurobindo submitted as part of the Aurobindo ANDA a Paragraph IV Certification, asserting that the claims of the '629 Patent are invalid and/or not infringed by the manufacture, use, offer for sale, or sale of Aurobindo's Proposed ANDA Product.

66. Aurobindo did not contend in its Notice Letter that the use of Aurobindo's Proposed ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would not infringe claim 1 of the '629 Patent.

67. Aurobindo has no reasonable basis to believe that the use of Aurobindo's Proposed ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would not infringe claim 1 of the '629 Patent.

68. The purpose of submitting the Aurobindo ANDA to the FDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, importation, and/or sale of Aurobindo's Proposed ANDA Product prior to the expiration of the '629 Patent.

69. Aurobindo's submission of the Aurobindo ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, importation, and/or offer for sale of Aurobindo's Proposed ANDA Product prior to the expiration of the '629 Patent was an act of infringement of the '629 Patent under 35 U.S.C. § 271(e)(2)(A).

70. Upon information and belief, Aurobindo intends to engage in the commercial manufacture, use, sale, importation, and/or offer for sale of Aurobindo's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of the Aurobindo ANDA and any amendments thereto, *i.e.*, prior to the expiration of the '629 Patent.

71. Upon information and belief, Aurobindo has knowledge of the '629 Patent at least because the '629 Patent is listed in the Orange Book for Lilly's Olumiant® (baricitinib) drug product. Notwithstanding this knowledge, Aurobindo continues to assert its intent to engage in the manufacture, use, offer for sale, importation, and/or sale of Aurobindo's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of the Aurobindo ANDA and any amendments thereto.

72. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '629 Patent when the Aurobindo ANDA and any amendments thereto are approved by selling its Proposed ANDA Product with a label that provides instructions to administer 1 mg and 2 mg baricitinib tablets for the treatment of rheumatoid arthritis in a manner that infringes claims of the '629 Patent, and will do so with specific intent to induce infringement

of the '629 Patent. Further upon information and belief, Aurobindo plans and intends to, and will, do so immediately and imminently upon approval.

73. Upon information and belief, Aurobindo knows that Aurobindo's ANDA Product is especially made or adapted for use in infringing the '629 Patent, and that Aurobindo's ANDA Product is not a staple article of commerce suitable for substantial noninfringing use. Upon information and belief, Aurobindo plans, intends to, and will, contribute to infringement of the '629 Patent immediately and imminently upon approval of the Aurobindo ANDA and any amendments thereto.

74. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '629 Patent, active inducement of infringement of the '629 Patent, and contribution to the infringement of the '629 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and (c).

75. Unless Aurobindo is enjoined from infringing the '629 Patent and actively inducing and contributing to infringement of the '629 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Aurobindo has infringed one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A) by submitting the Aurobindo ANDA to the FDA;

(b) A judgment that Aurobindo's making, using, offering to sell, selling, marketing, distributing, or importing into the United States of Aurobindo's Proposed ANDA Product prior to the expiration of the Asserted Patents will infringe, actively induce infringement of, and/or

contribute to infringement of one or more claims of the Asserted Patents under 35 U.S.C. §§ 271(a), (b), and/or (c);

(c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for Aurobindo to make, use, offer for sale, sell, market, distribute, or import Aurobindo's Proposed ANDA Product, or any product the use of which infringes the Asserted Patents, be not earlier than the latest expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A preliminary and/or permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Aurobindo, Aurobindo's affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in privity or concert with them, from making, using, selling, offering to sell, marketing, distributing, or importing Aurobindo's Proposed ANDA Product, or any product the use of which infringes one or more claims of the Asserted Patents, prior to the latest expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

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